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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/774,393	02/10/2004	Alan Leslie Cripps	CRIP3001C3/REF	1830

23364 7590 03/26/2007

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EXAMINER	
HAGHIGHATIAN, MINA	
ART UNIT	**PAPER NUMBER**
1616	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/26/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/774,393	CRIPPS ET AL.	
	Examiner	Art Unit	
	Mina Haghighatian	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 December 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *40-51 and 53-74* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *40-51 and 53-74* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/27/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of the Request for Reconsideration, TD and IDS filed on 12/27/06.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 40-51, 53-74 are rejected under 35 U.S.C. 103(a) as being unpatentable over McCarthy et al (WO 9824420).

McCarthy et al disclose a device for providing pharmaceutical doses comprising a container filled with a pharmaceutical composition including a pharmaceutically active agent in a **solution** of liquefied HFA 134a or HFA 227 and a carrier. The carrier can be an alcohol, polyalkoxy derivative, fatty acid, polyalkylene glycol, etc (see abstract). The preferred alcohol is **ethanol**, the preferred polyols include propylene glycol and glycerol and preferred polyalkylene glycol is polyethylene glycol. The composition may comprise up to **50%** or preferably **25%** w/w carrier (see entire page 5). The formulations may comprise a plurality of carriers (see page 6, lines 1-2).

McCarthy et al discloses that preferred agents for the said formulations include steroid s such as beclomethasone, betamethasone, flunisolide, budesonide, **fluticasone** etc (see page 7, lines 5-24). Examples 1-11 show various formulations comprising active agents, ethanol and other ingredients. Example 2 indicates a solution

formulations comprising the steroid BDP in an amount of 0.1%, ethanol in an amount of 7.5% and HFC-134a in an amount of 92.3%. It is disclosed that the BDP was dissolved in the ethanol and 0315 g of the resulting solution was placed in a canister and a valve assembly was sealed into the canister. Each expelled dose of the formulation is about **25 µl and provides 50 µl** of BDP (see page 14, line 6 to col. 15, line 1). Example 3 shows 5 formulations, formulation E comprises 0.1% BDP, 20.5% ethanol and 79.3% HFA 134a. Formulation D shows a formulation comprising 4.9% propylene glycol. the said solutions are placed in suitable canisters (see page 15). Examples 5 and 9 disclose formulations comprising 3% propylene glycol.

Although McCarthy et al does not exemplify a formulation comprising fluticasone propionate, it does teach solutions for inhalation comprising active agents such as steroids including fluticasone, ethanol, propellant and optionally a low volatility component such as polyethylene glycol. As such, It would have been obvious to one of ordinary skill in the art at the time the invention was made to have selected fluticasone propionate as the suitable active agent for the said solution formulations as taught by McCarthy. It has been shown that McCarthy et al meet all the limitations of the instant claims, thus McCarthy et al has provided sufficient disclosure to one of ordinary skill in the art to make and use the invention as claimed.

Claims 40-45, 51, 55, 57-62, 68-69 and 71-73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schultz et al (CA 2,094,266) in view of Paler (EP 0416951).

Schultz et al teach a pharmaceutical solution aerosol formulations comprising beclomethasone 17, 21 dipropionate, ethanol and a propellant selected form HFA 134a, HFA 227 or a mixture thereof (see abstract and page 2). The solution formulations are suitable for pulmonary administration (see page 2a).

Schultz et al discloses that the medicament will constitute about 0.02 to about 0.6% by weight of the total weight of the formulation. Ethanol is present in an amount effective to solubilize the beclomethasone 17, 21 dipropionate in the propellant. Preferably, ethanol constitutes about 1 to about 20 percent by weight of the total weight of the formulation. Ethanol will be present in an amount sufficient to dissolve substantially all of the medicament present in he formulation and to maintain the medicament present in the formulation and to maintain the medicament dissolved over time period (see page 3, lines 5-30).

Schultz et al also discloses that the formulations are substantially free of any surfactant. Furthermore, the formulations consist essentially of beclomethasone 17, 21 dipropionate, ethanol and propellant (see page 4). The aerosol device and method of making the solution and filling the canister is disclosed in page 5. Table 1 shows a few formulations. Schultz et al, teaching a steroid formulation lack disclosure on fluticasone propionate.

Palmer teaches formulations comprising salmeterol and fluticasone propionate for inhalation and nebulization. It is disclosed that the said formulations may be in solution form (see page 2).

It would have been obvious to one of ordinary skill in the art at the time the invention was made given the general teachings and formulations of Schultz et al on solution formulations comprising a corticosteroid such as beclomethasone 17, 21 dipropionate for inhalation to have looked for other active agents such as fluticasone dipropionate to prepare solution formulations for effective treatment of patients who need other medicaments. In other words merely substituting one active agent for another does not patentably distinguish claims form prior art.

Response to Arguments

Applicant's arguments filed 08/28/06, with respect to claims 40-51, 53-74 have been fully considered and are persuasive. As such the previous rejections under 35 USC 103(a) have been withdrawn.

Applicant states that during an Interview with Examiner and her supervisor an agreement was reached to allow the instant claims. However upon reconsideration, it was determined that certain references included in the IDS filed on 12/27/06 meet the limitations of the instant claims.

Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on 12/2/70/6 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609.04(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mina Haghighatian whose telephone number is 571-272-0615. The examiner can normally be reached on core office hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Mina Haghighatian
Patent Examiner
March 15, 2007

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